

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

PEPYS

Group Art Unit: 1617

Application No.: 09/737,544

Confirmation No.: 1521

Filed: December 18, 2000

Examiner: Shengjun WANG

Title: TREATMENT AND PREVENTION OF TISSUE DAMAGE

KATZ DECLARATION BY PROFESSOR MARK B. PEPYS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Mark B. Pepys, hereby declare as follows:

- (1) I am Professor of Medicine and Head, Department of Medicine, Hampstead Campus, Royal Free and University College Medical School, London, U.K., and have worked in the field of chemical, biological, and clinical investigation of C-reactive protein (CRP) for 30 years.
- (2) I am the sole inventor of U.S. Patent Application No. 09/737,544, entitled "Treatment and Prevention of Tissue Damage" ("the '544 application").
- (3) I have invented a method for selecting a pharmaceutical for treating or preventing CRP-mediated tissue damage in a subject comprising identifying and selecting a compound that inhibits the binding of CRP to an autologous or extrinsic ligand thereof, and a method for treating or preventing C-reactive protein (CRP)-mediated tissue damage comprising administering to a subject in need thereof an effective amount of a compound capable of inhibiting the binding of CRP to an autologous or extrinsic ligand thereof. Original claims 1-25 and 39-48 of the '544 application that were elected for examination are directed to embodiments of my invention pertaining to a method for treating or preventing CRP-mediated tissue

400314681v1

damage a subject in need thereof comprising administering to the subject an effective amount of phosphocholine or a derivative thereof that inhibits the binding of CRP to an autologous or extrinsic ligand thereof.

(4) I have read and am familiar with the official action issued by the U.S. Patent and Trademark Office and dated September 2, 2005, in connection with the '544 application.

(5) I make this declaration in response to the official action issued 2005, in which claims 1-25 and 42-56 were rejected under 35 U.S.C. § the claimed invention allegedly would have been obvious to a person o in the art at the time the invention was made, in view of Bhakdi et al. Thromb. Vasc. Biol., 1999, 19:2348-2354), in view of Griselli et al. (December 20, 1999, 190(12): 1733-1739), further in view of Yedgar et al. (U.S. Patent No. 5,064,817) and Wissner et al. (U.S. Patent No. 4,640,913).

(6) I have reviewed the above-identified references cited by the examiner, *i.e.*, Bhakdi et al. (1999), Griselli et al. (1999), Yedgar et al. (U.S. Patent No. 5,064,817) and Wissner et al. (U.S. Patent No. 4,640,913).

(7) The Griselli et al. publication, of which I am a co-author, relates to the invention that is disclosed in the '544 application, and describes experimental results that are disclosed in the '544 application. For example, Figures 1 and 2 and Tables 1 and 2 of the Griselli et al. reference are identical to Figures 1 and 2 and Tables 2 and 3 of the '544 application.

(8) Pursuant to 37 C.F.R. §1.132, I hereby declare that I am the sole inventor of the subject matter disclosed in the Griselli et al. publication. The other authors of the publication, Massimo Griselli, Jeffrey Herbert, Winston L. Hutchinson, Kenneth M. Taylor, Muhammed Sohail, and Thomas Krausz, worked under my direction and supervision and were not co-inventors. *See In re Katz*, 215 U.S.P.Q. 14 (CCPA 1982).

At the time the work reported in the Griselli et al. article was performed, Massimo Griselli was an M.S. (Surgery) student, and I was his supervisor; Jeffrey Herbert was a clinical scientist (a member of staff in the department); Winston Hutchinson was a Principle Research Fellow (also member of staff in the dept); Professor Kenneth Taylor was joint supervisor of Massimo Griselli (Dept. of Surgery); and Muhammed Sohail and Thomas Krausz (both of whom are histopathologists) were acting as collaborators.

The work reported in the Griselli et al. reference was entirely my idea, including the experimental approach, all aspects of the experiments and the writing of the manuscript. I organized a suitable team including members of his own laboratory and others with the necessary expertise. Thus I enlisted the collaboration of K. Taylor, the Professor of Cardiac Surgery, who provided M. Griselli, a trainee surgeon, to do the rat surgery, and T. Krausz, the Professor of Histopathology, who provided M. Sohail, a trainee histopathologist, to do the histology. The other authors thus made essentially technical contributions, albeit at a high level, rather than intellectual contributions to the work.

(9) I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and may jeopardize the validity of the application or any patent issued thereon.

MARK B. PEPYS

Date